

**UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

In the Matter of:

**Enrofloxacin for Poultry:
Withdrawal of Approval of
New Animal Drug Application
NADA 140-828**

FDA DOCKET: 00N-1571

**BAYER'S RESPONSE TO CVM'S MOTION TO WITHDRAW
GOVERNMENT EXHIBIT G-1557 AND ADD GOVERNMENT EXHIBIT G-1572**

In response to CVM's motion to withdraw Exhibit G-1557 and replace it with Exhibit G-1572, Respondent Bayer states as follows:

Bayer does not object to the Center for Veterinary Medicine's proposal to withdraw Exhibit G-1557 and replace it with G-1572 as long as CVM provides to Bayer an electronic copy of G-1572 conforming to the paper version and provides certain information about the document.

As demonstrated by comparing pages 1 and 4 of Exhibit G-1557 (Attachment 1) with analogous pages of the CVM-provided electronic version of the same data set (Attachment 2) it is clear that the current versions available to Bayer differ. The electronic version is missing numerous data columns (LLABNUM and LABNUM, for example) and does not have the patients' occupations (Column AL of G-1557). Bayer requests that if CVM is permitted to replace G-1557 with G-1572, that CVM be required to provide Bayer with an electronic version of G-1572 conforming to the new paper exhibit.

Additionally, Bayer seeks the identity of data column variables in the Exhibit G-1557/G-1572 data set. By seeking to submit the G-1557/G-1572 data set as part of its 21 CFR § 12.85 submission, CVM is necessarily representing either: that the document "relates to the issues

involved in the hearing” under § 12.85(2); or that it is “documentary data and information relied upon” by CVM under § 12.85(3). Bayer has repeatedly asked CVM for a key to the identity of variables in the data set columns (*See* Attachment 3, letter from Bayer counsel Gregory A. Krauss to CVM counsel Nadine Steinberg). CVM’s determination that G-1557/G-1572 is relevant or worth relying on must be based on something they have or something they saw. Yet CVM disclaims having any written key and refuses to provide one from the party generating the document. Bayer has no idea what the column variables in the data set mean. They have names like “CULTREAS,” “CAMPSTL,” “CAMPBLD” or “CAMPOTH” and are not self-evident. If CVM has or can readily obtain a key to defining the variables they should provide it for the record. At a minimum, CVM should explain why they cannot provide such a key. Otherwise CVM should not be able to use the document. It is clear that CVM believes this data set relates to the issues or contains data or information on which CVM will rely. CVM should disclose for the record any documents on which the relevance or reliance are based.

Similarly, Bayer seeks information relating to the genesis of the G-1557/G-1572 data set. How were the data generated? What protocol was used? Was there a questionnaire used and if so, what were the questions? Bayer has repeatedly sought this information from CVM. CVM disclaims having any protocol or questionnaire. It is unlikely that CVM could conclude that the data set is relevant or worthy of reliance without an understanding of how the data were collected. Yet CVM refuses to provide any protocol or questionnaire. Again, CVM should provide any information it has on the genesis of this data set or explain why it cannot.

In light of the above, Bayer requests that any order allowing CVM to substitute G-1572 for G-1557 also require CVM to provide the key to variables in G-1572 and provide the protocol and/or questionnaire from which the data were derived. A draft order is attached.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'R. Nicholas', written over a horizontal line.

Robert B. Nicholas
James H. Sneed
Gregory A. Krauss
M. Miller Baker
MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8000

CERTIFICATE OF SERVICE

I hereby certify that a copy of Bayer's Response to CVM's Motion to Withdraw Government Exhibit G-1557 and Add Government Exhibit G-1572 was e-mailed and also mailed, postage pre-paid, this 12th day of November 2002, to:


Kent D. McClure
Animal Health Institute
1325 G Street, N.W., Suite 700
Washington, D.C. 20005

I hereby certify that a copy of Bayer's Response to CVM's Motion to Withdraw Government Exhibit G-1557 and Add Government Exhibit G-1572 was e-mailed and also mailed, postage pre-paid, this 12th day of November 2002, to:

Nadine R. Steinberg, Esquire
Food and Drug Administration
Office of General Counsel (CGF-1)
5600 Fischers Lane, Room 7-77
Rockville, Maryland 20857

I hereby certify that a copy of Bayer's Response to CVM's Motion to Withdraw Government Exhibit G-1557 and Add Government Exhibit G-1572 was e-mailed, faxed and also mailed, postage pre-paid, this 12th day of November 2002, to:

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857



Robert B. Nicholas

**UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

In the Matter of:

**Enrofloxacin for Poultry:
Withdrawal of Approval of
New Animal Drug Application
NADA 140-828**

FDA DOCKET: 00N-1571

ORDER

By Motion filed October 31, 2002 the Center for Veterinary Medicine ("CVM") seeks to withdraw Exhibit G-1557 from Docket 00N-1571, and seeks to add Exhibit G-1572, which is a revised version of Exhibit G-1557. CVM seeks to withdraw Exhibit G-1557 in order to protect the personal privacy of patients enrolled in a Center for Disease Control and Prevention study.

The Center for Veterinary Medicine's Motion to Withdraw Exhibit G-1557 and add Exhibit G-1572 is HEREBY GRANTED; and it is further

ORDERED that CVM provide Bayer with an electronic version of G-1572, conforming to the new paper exhibit, no later than _____, 2002; and it is further

ORDERED that CVM submit to the docket a key identifying the data set variables in G-1572, or an explanation as to why it cannot, no later than _____, 2002; and it is further

ORDERED that CVM submit to the docket the protocol and questionnaire from which the data in Exhibit G-1572 were derived, or an explanation as to why it cannot, no later than _____, 2002.

DATED this the ____ day of November, 2002.

Daniel J. Davidson
Administrative Law Judge

CAMPYJS

	A	B	C	D	E	F	G	H	I	J	K	L
1	CASENUM	LLABNUM	PRELABN	LABNUM	INI	COUNTY	STATE	CULTD2	CULTREAS	CAMPSTL	CAMPBLD	CAMPOTH
2	0101	00000	00000D	3232	PET	WORCESTE	MA	09/24/89	1	1	2	2
3	0102	00000	00000D	3440	SON	WORCESTE	MA	01/31/90	1	1	2	2
4	0103	00000	00000D	3405	STE	WORCESTE	MA	01/21/90	1	1	2	2
5	0201	00000	00000D	3234	SUL	ESSEX	MA	10/05/89	1	1	2	2
6	0202	00000	00000D	3242	CRA	ESSEX	MA	10/25/89	1	1	2	2
7	0203	00000	00000D	3237	CAR	ESSEX	MA	11/15/89	1	1	2	2
8	0204	00000	00000D	3236	BEN	ESSEX	MA		1	1	2	2
9	0205	00000	00000D	3238	WAR	ESSEX	MA		1	1	2	2
10	0206	00000	00000D	3240	BON	ESSEX	MA		1	1	2	2
11	0207	00000	00000D	3233	CHR	ESSEX	MA	09/25/89	1	1	2	2
12	0208	00000	00000D	3365	GAS	ESSEX	MA	12/01/89	1	1	2	2
13	0209	00000	00000D	3368	HAR	ESSEX	MA	12/12/89	1	1	2	2
14	0210	00000	00000D	3366	MCP	ESSEX	MA		1	1	2	2
15	0211	00000	00000D	3367	BAR	ESSEX	MA	12/12/89	1	1	2	2
16	0212	00000	00000D	3369	MAR	ESSEX	MA	12/21/90	1	1	2	2
17	0213	00000	00000D	3406	PUR	ESSEX	MA	01/18/90	1	1	2	2
18	0214	00000	00000D	3402	BUC	ESSEX	MA	01/04/90	1	1	2	2
19	0215	00000	00000D	3404	STH	ESSEX	MA	01/24/90	1	1	2	2
20	0216	00000	00000D	3439	CUM	ESSEX	MA	01/25/90	1	1	2	2
21	0217	00000	00000D	3441	GAR	ESSEX	MA		4	1	2	2
22	0218	00000	00000D	3443	HOL	ESSEX	MA	02/10/90	1	1	2	2
23	0219	00000	00000D	3500	MCM	ESSEX	MA	02/26/90	1	1	2	2
24	0220	00000	00000D	3502	WIN	ESSEX	MA	03/11/90	1	1	2	2
25	0221	00000	00000D	3504	GON	ESSEX	MA	03/24/90	1	1	2	2
26	0222	00000	00000D	3503	ATW	ESSEX	MA	03/26/90	1	1	2	2
27	0223	00000	00000D	3540	WAR	ESSEX	MA	04/03/90	1	1	2	2
28	0224	00000	00000D	3542	CAN	ESSEX	MA	04/06/90	1	1	2	2
29	0225	00000	00000D	3543	FUS	ESSEX	MA	04/09/90	1	1	2	2
30	0226	00000	00000D	3544	BOY	ESSEX	MA	04/10/90	1	1	2	2
31	0227	00000	00000D	3545	LOD	ESSEX	MA	04/13/90	1	1	2	2
32	0228	00000	00000D	3547	SCA	ESSEX	MA	04/14/90	1	1	2	2
33	0229	00000	00000D	3546	JES	ESSEX	MA	04/17/90	1	1	2	2
34	0230	00000	00000D	3548	SCO	ESSEX	MA	04/19/90	1	1	2	2
35	0231	00000	00000D	3549	OCO	ESSEX	MA	04/19/90	1	1	2	2
36	0301	00000003	00000D	3246	SCO	WESTCHES	NY	10/10/89	1	1	2	2
37	0302	00000003	00000D	3247	MOT	WESTCHES	NY	10/14/89	1	1	2	2

CAMPYJS

	A	AI	AJ	AK	AL	AM	AN	AO	AP	AQ	AR	AS
1	CASENUM	CALAGE	SEX	RACE	OCCUP	ILL	ILLD2	ILLDAYS	FELTFEV	FEVER	FEVERMAX	NAUSEA
2	0101		22	2	1 RECORD TE		1 09/20/89	10	2	2	0	2
3	0102		68	2	1 SHELF-STO		1 01/30/90	17	1	1	0	2
4	0103				STUDENT		1 01/19/90	10	1	1	1030	1
5	0201		32	1	1 INSTALL W		1 10/03/89	5	1	2	0	1
6	0202				PHOTOGRA		1 10/23/89	8	1	1	1013	2
7	0203		1	1	1 1		10/13/89	5	1	2	0	2
8	0204		35	1	1 CONSTRUC		1 10/10/89	8	1	2	0	1
9	0205				SOFTWARE		1	4	2	2	0	2
10	0206		25	2	1 PHLOBOTO		1 10/19/89	14	2	2	0	2
11	0207				PLUMBER		1 09/21/89	6	1	1	0	1
12	0208				HOMEMAK		1 11/26/89	10	2	2	0	1
13	0209		67	2	1 RETIRED R		1 12/06/89	21	1	2	0	1
14	0210		55	2	1 BANK OFFI		1 11/27/89	3	1	1	1010	1
15	0211		35	2	1 COUNSELO		1 12/09/89	7	1	1	1030	1
16	0212		26	1	1 SALES REP		1 12/19/89	14	2	2	0	2
17	0213		47	2	1 ESTIMATO		1 01/15/90	5	1	1	1020	2
18	0214		30	1	1 TEACHER		1 12/30/90	10	1	0	2	2
19	0215		34	1	1 MECHANIC		1 01/19/90	13	1	1	1030	1
20	0216		23	2	1 PAINTER		1 12/30/89	7	1	1	1020	1
21	0217				PART TIME		1 01/16/90	6	2	2	0	2
22	0218		23	2	1 FISHPACKE		1 02/02/90	14	1	2	0	1
23	0219				ENGINEER		1 02/22/90	4	1	1	1020	2
24	0220		27	1	1 AUTO MEC		1 03/05/90	30	1	2	0	1
25	0221		22	1	3 BENCHWO		1 03/24/90	4	1	1	1030	1
26	0222		3	2	1 CHILD		1 03/23/90	2	1	1	1020	2
27	0223		31	1	1 SALES		1 03/30/90	10	1	1	1040	1
28	0224		32	2	1 RESPIRATO		1 04/02/90	10	1	2	0	1
29	0225		21	1	1 TESTMAN		1 04/04/90	10	1	1	1000	1
30	0226		69	1	1 RETIRED		1 03/29/90	17	2	2	0	2
31	0227		28	2	1 ATTORNEY		1 04/10/90	7	1	0	1	1
32	0228		34	2	1 HOUSEWIF		1 04/11/90	7	2	2	0	2
33	0229		26	2	1 OFFICE MA		1 04/13/90	14	1	1	1010	2
34	0230		3	2	1 CHILD		1 04/17/90	3	2	2	0	2
35	0231		65	1	1 SALES REP		1 04/16/90	20	1	1	1020	2
36	0301		49	2	1 HOUSEWIF		1 10/06/89	6	2	0	1	2
37	0302		20	2	1 OFFICE AS		1 10/11/89	7	1	1	1020	1

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	CASENUM	PRELABN	COUNTY	STATE	CULTD2	CULTREAS	CAMPSTL	CAMPBLD	CAMPOTH	CAMPSPEC	HOSP	HOSPDAYS	DIE
2	0101	00000D	WORCEST	MA	09/24/89	1	1	2	2	2	2	1	
3	0102	00000D	WORCEST	MA	01/31/90	1	1	2	2	2	2	1	
4	0103	00000D	WORCEST	MA	01/21/90	1	1	2	2	2	2	1	
5	0201	00000D	ESSEX	MA	10/05/89	1	1	2	2	2	2	1	2
6	0202	00000D	ESSEX	MA	10/25/89	1	1	2	2	2	2	1	
7	0203	00000D	ESSEX	MA	11/15/89	1	1	2	2	2	2	2	2
8	0204	00000D	ESSEX	MA		1	1	2	2	2	2	1	
9	0205	00000D	ESSEX	MA		1	1	2	2	2	2	1	
10	0206	00000D	ESSEX	MA		1	1	2	2	2	2	2	1
11	0207	00000D	ESSEX	MA	09/25/89	1	1	2	2	2	2	1	
12	0208	00000D	ESSEX	MA	12/01/89	1	1	2	2	2	2	1	1
13	0209	00000D	ESSEX	MA	12/12/89	1	1	2	2	1	7	2	2
14	0210	00000D	ESSEX	MA		1	1	2	2	2	2	1	1
15	0211	00000D	ESSEX	MA	12/12/89	1	1	2	2	2	2	1	
16	0212	00000D	ESSEX	MA	12/21/90	1	1	2	2	2	2	1	
17	0213	00000D	ESSEX	MA	01/18/90	1	1	2	2	2	2	1	
18	0214	00000D	ESSEX	MA	01/04/90	1	1	2	2	2	2	1	
19	0215	00000D	ESSEX	MA	01/24/90	1	1	2	2	1	7	2	1
20	0216	00000D	ESSEX	MA	01/25/90	1	1	2	2	2	2	1	1
21	0217	00000D	ESSEX	MA		4	1	2	2	2	2	2	2
22	0218	00000D	ESSEX	MA	02/10/90	1	1	2	2	2	2	1	
23	0219	00000D	ESSEX	MA	02/26/90	1	1	2	2	2	2	2	2
24	0220	00000D	ESSEX	MA	03/11/90	1	1	2	2	2	2	1	2
25	0221	00000D	ESSEX	MA	03/24/90	1	1	2	2	2	2	1	
26	0222	00000D	ESSEX	MA	03/26/90	1	1	2	2	2	2	1	
27	0223	00000D	ESSEX	MA	04/03/90	1	1	2	2	2	2	1	
28	0224	00000D	ESSEX	MA	04/06/90	1	1	2	2	2	2	1	
29	0225	00000D	ESSEX	MA	04/09/90	1	1	2	2	2	2	1	
30	0226	00000D	ESSEX	MA	04/10/90	1	1	2	2	1	7	2	1
31	0227	00000D	ESSEX	MA	04/13/90	1	1	2	2	2	2	1	
32	0228	00000D	ESSEX	MA	04/14/90	1	1	2	2	1	1	2	1
33	0229	00000D	ESSEX	MA	04/17/90	1	1	2	2	2	2	1	
34	0230	00000D	ESSEX	MA	04/19/90	1	1	2	2	2	2	1	
35	0231	00000D	ESSEX	MA	04/19/90	1	1	2	2	2	2	2	1

BAYER11

	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ
1	INTERV	CALAGE	SEX	RACE	ILL	ILLD2	ILLDAYS	FELTFEV	FEVER	FEVERMAX	NAUSEA	VOMIT	DIAR
2	1	22	2	1	1	09/20/89	10	2	2	0	2	2	1
3	1	68	2	1	1	01/30/90	17	1	1	0	2	2	1
4						01/19/90	10	1	1	1030	1	1	1
5	1	32	1	1	1	10/03/89	5	1	2	0	1	1	1
6						10/23/89	8	1	1	1013	2	2	1
7	2	1	1	1	1	10/13/89	5	1	2	0	2	2	1
8	1	35	1	1	1	10/10/89	8	1	2	0	1	2	1
9	2	2	2	2	2	1	2	2	1	2	1	3	1
10	1	25	2	1	1	10/19/89	14	2	2	0	2	2	1
11						09/21/89	6	1	1	0	1	2	1
12						11/26/89	10	2	2	0	1	1	1
13	1	67	2	1	1	12/06/89	21	1	2	0	1	2	1
14	1	55	2	1	1	11/27/89	3	1	1	1010	1	1	1
15	1	35	2	1	1	12/09/89	7	1	1	1030	1	1	1
16	1	26	1	1	1	12/19/89	14	2	2	0	2	2	1
17	1	47	2	1	1	01/15/90	5	1	1	1020	2	2	1
18	1	30	1	1	1	12/30/90	10	1	0	2	2	1	7
19	1	34	1	1	1	01/19/90	13	1	1	1030	1	1	1
20	1	23	2	1	1	12/30/89	7	1	1	1020	1	2	1
21						01/16/90	6	2	2	0	2	2	1
22	1	23	2	1	1	02/02/90	14	1	2	0	1	1	1
23						02/22/90	4	1	1	1020	2	2	1
24	1	27	1	1	1	03/05/90	30	1	2	0	1	2	1
25	1	22	1	3	1	03/24/90	4	1	1	1030	1	1	1
26	2	3	2	1	1	03/23/90	2	1	1	1020	2	2	1
27	1	31	1	1	1	03/30/90	10	1	1	1040	1	2	1
28	1	32	2	1	1	04/02/90	10	1	2	0	1	2	1
29	1	21	1	1	1	04/04/90	10	1	1	1000	1	1	1
30	1	69	1	1	1	03/29/90	17	2	2	0	2	2	1
31	1	28	2	1	1	04/10/90	7	1	0	1	1	1	6
32	1	34	2	1	1	04/11/90	7	2	2	0	2	1	1
33	1	26	2	1	1	04/13/90	14	1	1	1010	2	2	1
34	2	3	2	1	1	04/17/90	3	2	2	0	2	2	1

A Partnership Including
Professional Corporations
600 Thirteenth Street, N.W.
Washington, D.C. 20005-3096
202-756-8000
Facsimile 202-756-8087
www.mwe.com

Gregory A. Krauss
Attorney at Law
gkrauss@mwe.com
202-756-8263

Boston
Chicago
London
Los Angeles
Miami
Moscow
New York
Orange County
Silicon Valley
Vilnius
Washington, D.C.

MCDERMOTT, WILL & EMERY

VIA FACSIMILE & FIRST-CLASS MAIL

October 29, 2002

Nadine R. Steinberg, Esquire
Food and Drug Administration
Office of General Counsel (CGF-1)
5600 Fischers Lane, Room 7-77
Rockville, Maryland 20857

Re: Bayer AG
Enrofloxacin Hearing; Docket 00N-1571
Our File No.: 48250-013

Dear Nadine:

This shall confirm our telephone conversation on October 28, 2002 regarding document G-1557. CVM wants to replace G-1557, a paper copy of the Sobel human isolate *Campylobacter* data set, with a paper version that removes identifying initials of the subjects and removes that portion of the subjects' occupations that may identify any subject with specificity. Bayer generally has no conceptual objection with CVM's proposal so long as CVM provides an electronic version of the data set conforming to the new paper exhibit.

Bayer does have concerns surrounding use of the Sobel data set by CVM in this hearing. Bayer has requested the Sobel survey protocol, questionnaire and keys to the variables in the data set. Bayer has sought these items through the FOIA process with CDC and through requests to CVM in the context of this litigation on a conference call September 6, 2002 and in our stipulation meet and confer on September 17, 2002. CVM disclaims having any of the requested information. Meanwhile, Bayer's FOIA request has been stymied by CDC and CVM has stated it will not get involved in the FOIA process. I asked for confirmation from you in writing that CVM does not have the protocol, questionnaire and variable keys and that CVM will not facilitate Bayer's obtaining them.

Bayer is concerned and, frankly, surprised that CVM will rely on the Sobel data set in any way at the hearing without this information. If Bayer does not get the protocol, questionnaire, and variable keys, Bayer may be forced to file a motion in limine seeking to

Nadine R. Steinberg, Esquire
October 29, 2002
Page 2

preclude use of the Sobel data set at the hearing and seeking to remove the data set from the record.

Sincerely,

A handwritten signature in black ink, appearing to read "Gregory A. Krauss". The signature is fluid and cursive, with a long horizontal stroke at the end.

Gregory A. Krauss

GAK:jeh